UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re ELAN CORPORATION SECURITIES LITIGATION	:	Master File No. 1:08-cv-08761-AKH

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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CASES

Defendants Elan Corporation, plc ("Elan"), G. Kelly Martin, and Lars Ekman (the "Defendants") respectfully submit this reply memorandum of law in further support of their motion to dismiss the Consolidated Complaint for Violations of the Federal Securities Laws (the "Complaint") and in response to Plaintiffs' opposition thereto ("Opp."). Unless otherwise defined herein, terms used are as defined in Defendants' Memorandum of Law in support of their motion ("Defs' Mem."). Defendants will not repeat herein all the arguments made in their opening memorandum, but instead will focus on the arguments to which Plaintiffs attempted a response.

PRELIMINARY STATEMENT

Plaintiffs' opposition confirms their Complaint is based on little more than erroneous speculation coupled with a stock drop. Neither is sufficient to plead fraudulent statements or fraudulent intent under the PSLRA.

Plaintiffs' claim that the May 21, 2007 announcement by Elan and Wyeth of their intention to commence Phase III trials of bapineuzumab was misleading relies upon the Complaint's unfounded allegations that (i) Elan and Wyeth's internal criteria for commencing Phase III trials were that bapineuzumab "outperform" placebo on the ADAS-cog and DAD tests (although they do not say according to what metric, what time period, what dose, or whether efficacy signals had to be observed in the total population or could be observed in important subgroups), and (ii) that these criteria were not met in the interim review. There are no public statements from which Plaintiffs purport to derive these allegations, and Plaintiffs do not claim that they obtained them from a confidential source with knowledge. As Plaintiffs acknowledge, neither the interim criteria nor the interim data were ever publicly disclosed. Plaintiffs' claim that reasonable investors could have been misled by statements that were never made defies logic. Plaintiffs may not be required to plead evidence, but they cannot circumvent the strict mandate of the PSLRA that fraud must be pleaded with particularity by guessing.

That Plaintiffs' allegations are without basis is manifested by their assumption – permeating their Complaint – that the interim data were the same as, or less favorable than, the final results of the Phase II trial. This conclusion is belied by those documents upon which the Complaint relies. Plaintiffs fail to apprehend that, as publicly disclosed by Elan and Wyeth and as stated in the Complaint, the Phase II trial was a multiple ascending dose trial. This meant that at the time of the interim review, far more data was available for the lower doses than for the higher doses. As shown by the final Phase II data presented at the July 29, 2008 ICAD conference, the data from the two lowest dose cohorts did clearly "outperform placebo" and were "strong" and "clinically meaningful" (or even "spectacular," although Plaintiffs continue to attribute that word only to Wyeth).

Plaintiffs' allegation that Elan and Wyeth's June 17, 2008 "top-line" release was materially misleading is equally deficient and directly contradicted by the documents on which their Complaint relies. Elan and Wyeth did not "cherry-pick" only good data to include in the June 17 release, but rather prominently disclosed the most negative, material aspect of the final Phase II results – that is, that the data had failed to achieve statistical significance on the pre-defined efficacy endpoints. The release otherwise included both favorable and unfavorable top-line results and advised investors that the detailed results would be presented at ICAD. In their opposition, Plaintiffs do not dispute Elan's arguments as to why the alleged omitted information was not material. Instead, they point to Elan's stock price movement and certain analysts' general reactions as their sole response, thereby revealing the substance of their pleadings as classic "fraud by hindsight."

As to scienter, Plaintiffs do not attempt to satisfy the strict pleading requirements of the PSLRA and instead merely embellish upon their fallacious speculation. Rather than support a "strong inference" of scienter, "cogent and at least as compelling as any opposing inference of nonfraudulent intent," *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 309-10 (2007), their motive allegations lack any semblance of plausibility. As demonstrated in Defendants' opening memorandum, Elan and Wyeth had specific, non-fraudulent reasons for the content and

manner of their disclosures concerning the Phase II trial. While advising investors in a timely manner of major developments in their business planning for bapineuzumab, Elan and Wyeth needed to keep the Phase II trial blinded and, with respect to the final results, were proceeding in accordance with a publicly disclosed plan to present the detailed results of the Phase II trial in late July 2008 at a major scientific conference (ICAD). Plaintiffs' theory of fraudulent intent requires the unreasonable inferences that Elan and Wyeth initiated hugely expensive Phase III trials while knowing bapineuzumab had "failed" the interim review, and that Elan and Wyeth made misleading disclosures about the Phase II results on June 17, 2008 while knowing that their misrepresentations would be exposed a mere six weeks later at ICAD. This would be implausible conduct for just one public company, but Plaintiffs' allegations require the even more bizarre inference that it was engaged in by both Elan and Wyeth.

Plaintiffs' only effort to plead a motive for such conduct – that Defendants misrepresented results in order to defraud doctors and patients into enrolling in Phase III trials – was so obviously inadequate that Plaintiffs now deny they ever made motive allegations and argue that their theory of scienter depends on recklessness alone. But this theory also fails. Rather than plead with particularity facts and circumstances suggesting Defendants had an obvious duty to disclose those matters Plaintiffs allege were misleadingly omitted (which is what is required to show recklessness for material omissions), Plaintiffs merely repeat their entirely speculative allegations that Defendants' statements were misleading. This is insufficient, and is not at all salvaged by Plaintiffs' attempted misdirection via their preposterous assertion that Defendants and Wyeth recklessly withheld information to defraud doctors and prospective clinical trial enrollees. That Elan simply adhered to the publicly announced pre-specified timetable for disclosure of the Phase II results – as required to maintain the integrity of the Phase II data, to comply with ICAD's requirements, and to honor Elan's agreement with Wyeth – is far more plausible, and cannot be found reckless.

Plaintiffs' failure to plead any factual basis for their allegations is fatal, and exposes the sole support for their claims as consisting of nothing other than faulty, hindsight-based speculation. This case should be dismissed, without leave to amend.

ARGUMENT

I. Plaintiffs Fail To State a Claim That the May 21, 2007 Press Release Was Misleading

A. Plaintiffs Fail To Plead Falsity with Sufficient Particularity Under the PSLRA

Plaintiffs' claim that the May 21, 2007 press release was materially misleading hinges on their conclusory allegation that "bapineuzumab failed to outperform placebo using the ADAS-cog and DAD tests in the interim review as required by Elan and Wyeth's prior agreement." Opp. at 18. Because Elan and Wyeth never disclosed the criteria for the interim review, Plaintiffs' allegation is nothing more than speculation about what the criteria were and how the interim results compared to them. Under the PSLRA, a securities fraud complaint must contain well-pleaded facts that set forth with particularity what statements were false and why they were false when made. Defs' Mem. at 28. While Plaintiffs need not plead evidence at this stage of the proceedings, they are not relieved of the PSLRA's requirement that they plead with particularity. *See, e.g., In re Navarre Corp. Sec. Litig*, 299 F.3d 735, 744-45 (8th Cir. 2002) (holding that even if "the subject matter of the fraud is uniquely within the defendants' knowledge or control … investors must plead with particularity the who, what, when, where and how of [the] alleged scheme").

To plead a material misrepresentation based on Defendants' alleged possession of confidential information contrary to their public statements, Plaintiffs "must give corroborating details" to establish why the confidential information indicated Defendants' statements were false when made. *San Leandro Emerg. Med. Grp. Profit Sharing Plan v. Philip Morris Co.*, 75 F. 3d 801, 812 (2d Cir. 1996) ("Plaintiffs' unsupported general claim of the existence of confidential company sales reports that revealed the larger decline in sales is insufficient to

survive a motion to dismiss."). The court in *Ladmen Partners v. Globalstar*, No. 07 Civ. 0976 (LAP) 2008 WL 4449280, at *16 (S.D.N.Y. Sept. 30, 2008), also found a failure to plead fraud with particularity, holding that allegations of confidential reports that allegedly contained information indicating that defendant had made misleading public statements were too generalized and lacked corroborating details.

Here, Plaintiffs' allegation about what the criteria were for the interim review is not derived from any public statements of Elan or Wyeth, and Plaintiffs do not allege that the allegation is based upon information from a confidential source with knowledge. Plaintiffs' claims are based on speculative and conclusory allegations about what the interim criteria were and how the interim data compared to them.[1] They fail to plead fraud with particularity and for that reason their claim should be dismissed.

B. The May 21, 2007 Release Could Not Have Misled Reasonable Investors Because the Criteria for the Interim Review Were Not Disclosed

Even if Plaintiffs had adequately pleaded that the interim review did not meet the criteria they allege, namely, that bapineuzumab failed to "outperform placebo using the ADAS-cog and DAD tests," Plaintiffs still have failed to state a claim because Elan and Wyeth never announced what the criteria were – not in terms of the tests used, the metrics applied to measure performance, or the effect on any subgroups in the patient population. Investors therefore could not have been misled into believing that any particular hurdle had been met because they were never advised of any particular hurdles.

In an attempt to fix this major flaw in their Complaint, Plaintiffs argue that Elan's statements that the results would need to be "strong" and "clinically meaningful" in order for

[1] That Plaintiffs have no factual basis for their claims of what the interim criteria were (*i.e.*, that they are guessing) is also evident from their confusion about what the tests measured. Plaintiffs state that the interim criteria related to four clinical endpoints to the trial – cognition, memory, quality of life and imaging – and then assert that '[t]hose "criteria were measured by the ADAS-cog and DAD cognitive tests used in the review." Opp. at 2. Obviously, cognitive tests are not "imaging" techniques; the imaging in the trial was done by MRIs. *See* Ex. W at 9. In addition, contrary to Plaintiffs' assertion, the DAD does not measure cognition, but quality of life. *See* Defs' Mem. at 11 n.7.

Elan and Wyeth to proceed to Phase III were a "proxy" for a statement that bapineuzumab would have to outperform placebo on the ADAS-cog and DAD tests. Opp. at 28. Plaintiffs apparently hope that this use of legalese will help obscure the fact that their Complaint is based on a public statement that was never made.

It does not. Elan and Wyeth's public disclosures made it absolutely clear that they were not announcing what the criteria were for the interim review. As Dr. Ekman stated at the January 9, 2007 conference, "We haven't been specific on which endpoint should move, how and when," but only that they were looking at endpoints that they believed would be meaningful in the regulatory process. Ex. D at 11. Elan's statements also made clear that they were not announcing the metrics to be used in the interim review, other than to indicate that they did not necessarily include statistical significance:

> What we've given the independent review group is very specific criteria that we're looking for. And we came up with that criteria by looking at a vast array of data, some of which I went through a little while ago that lets us anticipate which of these endpoints are going to move when and to what amplitude. And we're trying to do it in a way that therefore helps us design the Phase III trial with more specificity. And we're also trying to do it in a way that preserves the integrity of the current Phase II.

Ex. D at 9. At the May 1, 2008 conference, Mr. Martin again stated that they had not revealed the criteria used in the interim review and emphasized the number of factors that went into determining those criteria:

> Spectacular is probably in the eyes of the beholder, but what we said before we moved into Phase III, that we would need to see clinically meaningful data. We have looked at with Wyeth and ourself -- when I say we, Wyeth and ourselves, we looked at all the immunotherapeutic information, going back to the original IA in 1792. Looking at the Phase I data, looking at the interim Phase II data, et cetera.
>
> When we took an interim look, we clearly were looking for some specific things from a clinical point of view. There was a number of end points that we were looking at. We looked at it at a period of time that was still fairly early on in the Phase II. So we both - we looked for both specific points and specific trends in certain things and we put that together and we had discussions with both the European agency and the U.S. agency, the collective decision was we should move to a Phase III, simultaneously.

Ex. M at 2.

Plaintiffs cite two analyst reports to support their assertion that reasonable investors could have been misled (Opp. at 18), yet both explicitly acknowledged that any conclusions about the interim data and the interim criteria were speculative. The May 21, 2007 Davy Research report stated that "[n]o data have been disclosed" and "[t]he Phase II study remains blinded," while the July 31, 2007 Natixis Bleichroeder report stated that "there has been much speculation as to how good the data are, given that the trial is still blinded." Ex. H at 1. The Natixis Bleichroeder report stated that Elan and Wyeth's statements that the data would have to be "highly clinically relevant" to proceed to Phase III did not mean statistically significant. Ex. H at 10.

Because Elan and Wyeth expressly and repeatedly stated that the Phase II data would remain blinded, no reasonable investor could have drawn any concrete conclusions about the interim criteria sufficient to be misled based on the speculation of analysts. Elan and Wyeth did not disclose the criteria used in the interim review, and even the analysts relied on by Plaintiffs acknowledged that their speculation about the results was just that. It is insufficient to plead a claim of fraud.

C. The Complaint Does Not Adequately Allege That the May 21, 2007 Press Release and Related Statements Were False or Misleading; on the Contrary, the Inference from the Documents Relied on in the Complaint Is That the Criteria Alleged by Plaintiffs Were Met

Even if Plaintiffs' allegation concerning the criteria for the interim review were properly pleaded, Plaintiffs would still fail to state a claim because they have not adequately alleged that the criteria were not met. Instead, their allegations are completely speculative and conclusory – and such allegations are contradicted by the documents on which they rely in the Complaint. The only inference that can be drawn from those documents is that the data available at the time of the interim review met Plaintiffs' criteria and were strong, clinically meaningful, and even "spectacular."

Lacking any factual basis for their assertion that bapineuzumab failed the interim review in the spring of 2007, Plaintiffs resort again to speculation to argue that the data from the interim review of the Phase II data showed that bapineuzumab did not outperform placebo on ADAS-cog and DAD. But since it is only uninformed speculation, they confine it to a footnote, as follows:

> If Defendants are suggesting that the interim data satisfied the Companies' 'very specific criteria' even though the final data did not, that is very unlikely as a factual matter**.** As the Complaint alleges, 'Although the Phase 2 Study showed bapineuzumab to outperform placebo in some patients over 18 months, there was no short-term advantage for bapineuzumab.' ¶ 14(d). Thus, any data showing a positive effect of the drug were more likely to be evident at the end of the study, rather than earlier, upon the interim look.

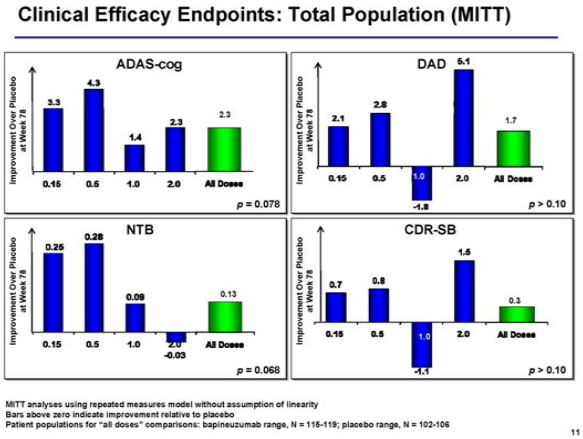
Opp. at 23 n.14. The erroneous assumption underlying Plaintiffs' speculation is that the four dose cohorts in the three-year study started and ended at the same time, and so the "end of the study" for all of the cohorts occurred after the interim review of the Phase II data was done in the spring of 2007. The basic documents concerning the Phase II trial relied on and quoted in the Complaint indicate that (i) that assumption is simply wrong, and (ii) when the assumption is corrected, it is clear that the interim review showed that bapineuzumab was outperforming placebo on ADAS-cog, DAD, and every other test used in the trial.

Plaintiffs' speculation ignores the fact that the Phase II trial was a "multiple ascending dose trial," which was repeatedly disclosed to the public. Compl. ¶ 37 (quoting Mr. Martin's statement at the January 9, 2007 JP Morgan conference that the Phase II trial was a "multiple ascending dose trial").[2] As explained by Dr. Ekman at the January 9, 2007 conference, the Phase II trial was "a dose-escalation trial, so you start with the very low doses and then you move upward. And you start to look at the low doses at the shortest possible time and then you move upwards." Compl. ¶ 37 (quoting Ex. D at 6). The four doses administered in the trial were 0.15 mg/kg, 0.5 mg/kg, 1.0 mg/kg, and 2.0 mg/kg, and a final efficacy assessment for each patient

[2] *See also* Ex. F at 1 (May 21, 2007 release stating Phase II trial was a "multiple ascending dose study of 4 cohorts"); Ex. J at 15 (February 28, 2008 Elan Form 20-F): Ex. N at 2 (June 17, 2008 press release); Ex. W at 4 (ICAD presentation).

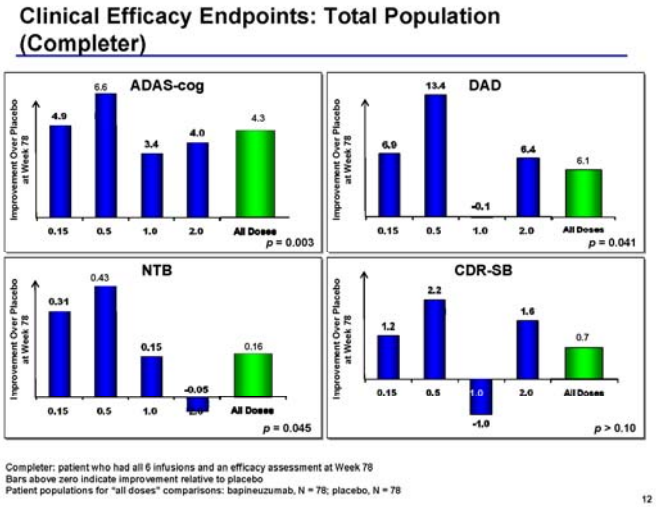
was done 78 weeks (18 months) after the initial dosing. Ex. N. at 2; Ex. W at 4. Because it was a dose-escalation trial, the patients in the lower-dose cohorts were enrolled and dosed earlier than the higher-dose cohorts and, naturally, reached their final, week-78 efficacy assessments earlier than the patients in the higher-dose cohorts. At the time of the interim look in the spring of 2007, the Phase II trial had been running for about two years and would continue for another year, until April 2008. Compl. ¶ 33. Because of the staggered start for the dose cohorts, at the time of the interim look in the spring of 2007, there was necessarily more data available concerning the results for the lower doses tested in the trial (0.15 mg/kg and 0.5 mg/kg) than for the higher doses (1.0 mg/kg and 2.0 mg/kg).

And, as set forth in the Phase II results presented at ICAD, those lower dose cohorts performed extremely well – clearly meeting Plaintiffs' alleged criteria and constituting "strong," "clinically meaningful," and even "spectacular" results. Included in the presentation at ICAD was a slide showing the efficacy results in the total Phase II population, grouped by dose cohort:



Ex. W at 11. As shown in that slide, the two lower doses (0.15 mg/kg and 0.5 mg/kg) outperformed placebo across every endpoint (ADAS-cog, DAD, NTB, and CDR-SB) in the total population. The results shown for the 0.5 mg/kg dose are particularly striking: an impressive 4.3 point improvement over placebo in ADAS-cog and 2.8 improvement over placebo in DAD (even taking into account the fact that 95 percent of the patients in the trial continued to take approved drugs for Alzheimer's during the trial (Ex. W at 6; Ex. X at 3)).

The results shown among the "completers" (the patients who received all six intended doses of drug/placebo over the 18-month assessment period) were even more compelling: a stunning 6.6 point improvement over placebo in ADAS-cog and a 13.4 point improvement over placebo in DAD in the 0.5 mg/kg dose cohort.



Ex. W at 12.

Accordingly, while the final results of the entire Phase II trial are fairly characterized as "strong" and "clinically meaningful" (*see* Defs' Mem. at 29-30), the only inference that can be drawn from the documents on which the Complaint relies is that the results at the time of the interim review were even stronger – and that bapineuzumab was outperforming placebo on ADAS-cog and DAD. Plaintiffs' erroneous speculation to the contrary is not supported by the documents relied on in the Complaint, but is instead contradicted by them.

Nor does the Complaint adequately allege a claim based on Elan's statements that the data would need to be "strong" or "clinically meaningful" in order to proceed to Phase III. As a preliminary matter, these pre-Class Period statements are non-actionable opinion or immaterial corporate "puffery." *See, e.g.*, *Glaser v. Enzo Biochem, Inc.*, 303 F. Supp. 2d 724, 735 (E.D. Va. 2003) (defendant's statement that "it's all over, but the shouting" with regard to Phase I results was a non-actionable "'puffing' statement expressing enthusiasm about the prospects of the HIV/AIDS protocol" despite data's failure to satisfy standard FDA markers of efficacy for HIV

drugs). Elan thus had no "duty to update" these statements of corporate optimism. Defs' Mem. at 32-33.[3] Even if it had had such a duty, the Complaint fails to allege facts to show that Elan and Wyeth did not consider the data on the interim review "strong" and "clinically meaningful." Defs' Mem. at 29-30.[4]

Plaintiffs' sole effort to establish a materially false statement is to point to a 12 percent increase in Elan's stock price after the May 21, 2007 announcement. Opp. at 17 and 25 n.16. This is insufficient. First, stock price reaction alone is insufficient evidence of materiality. *See, e.g., United States v. Bilzerian*, 926 F. 2d 1285, 1287 (2d Cir. 1991). Second, the commencement of Phase III trials in itself was a positive development, indicating a belief on the part of both Elan and Wyeth that the drug's prospects for success merited the investment of hundreds of millions of dollars in large, expensive, and complex Phase III trials.

Plaintiffs also argue that, even though there were no affirmative misstatements in the May 2007 release, the context of the release made it misleading, given Elan's prior statements that Elan and Wyeth would proceed to Phase III trials only if an interim look showed data that met certain internal criteria and were "strong" and "clinically meaningful." Opp. at 20. But it is Plaintiffs who ignore context. Phase II trials are not typically powered to establish statistical

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[3] This case is unlike *In re GeoPharma, Inc. Securities Litigation*, 399 F. Supp. 2d 432 (S.D.N.Y. 2005) (Opp. at 18-19), in which the defendant announced it was developing a "drug" to treat mucositis, but later realized its product was in fact a medical "device." Defendants nonetheless issued a press release announcing it had received FDA marketing approval for a "prescription product." *Id.* at 437. The court held a reasonable investor could have been misled by "failing to absorb the distinction between the terms 'drug' and 'prescription product' . . . given the context of [defendant's] previous statements." *Id.* at 447. In *GeoPharma*, defendant's later statements were rendered misleading because it had previously described its product as a "drug," a term that definitively references a very specific regulatory framework. Here, not only are there no definitive reference points for the terms "strong" or "meaningful," but the context for them was the discussion of whether to commence and how to design a Phase III trial.

[4] Plaintiffs' reliance on *Bilhofer v. Flamel Technologies, SA*, 663 F. Supp. 2d 288 (S.D.N.Y. 2009), is thus misplaced; in that case the court held that the defendant's statements that its program was a "success" and "interest in both technologies have never been higher" were not puffery because plaintiffs had alleged facts sufficient to show defendants could not have had a reasonable basis for those statements. *See id.* at 299. Plaintiffs have not done so here.

significance,[5] and the 234-patient Phase II trial for bapineuzumab was no exception. As the May 21, 2007 press release stated, "The primary objective of the trial [was] to assess the safety of bapineuzumab." Ex. F; *see also* Ex. W (ICAD presentation) at 4 ("Primary objective: evaluate safety and tolerability in patients with mild to moderate AD. Secondary objective: evaluate efficacy in patients with mild to moderate AD."). Elan and Wyeth's public statements made clear that the interim review was undertaken not to predict the statistical significance of the final Phase II data on its pre-specified efficacy endpoints, but rather to determine whether there was enough data to support the design and initiation of Phase III trials. *See, e.g.*, Ex. D at 9 ("What we've given the independent review group is very specific criteria that we're looking for … And we're trying to do it in a way that therefore then helps us design a Phase III with more specificity."); Ex. D at 4 ("We have [agreed with Wyeth and the FDA] … to look at parts of the data in a very controlled manner [to] allow us to tease out information that will help us design the follow-on Phase III trial."). As Plaintiffs themselves say, "Elan and Wyeth agreed that they would conduct an 'interim review' of the Phase 2 results before the study was complete to determine whether and how to proceed to Phase 3 studies." Opp. at 6.[6]

Mr. Martin's comments at the May 1, 2008 conference were consistent with this context and could not have led anyone to believe that bapineuzumab was on track for filing for FDA approval based on statistically significant proof of efficacy from the Phase II trial. The Phase II trial was completed in April 2008, and Mr. Martin did not yet know the full results on May 1, 2008. Ex. M at 3.[7] Contrary to Plaintiffs' argument, Mr. Martin's comments did not suggest that

[5] *See Padnes v. Scios Nova, Inc.*, No. Civ. 95-1693, 1996 WL 539711, at * n.1 ("A phase II study is intended to gain preliminary evidence of the efficacy of the drug within a range of doses … A phase III study is conducted to obtain sufficient data for statistical proof of both safety and efficacy.").

[6] Because one of the purposes of a Phase II trial is to obtain sufficient information to design a meaningful Phase III trial that could lead to FDA approval of a new drug, Plaintiffs' suggestions of wrongdoing based on the design of the Phase III trial are meritless. Opp. at 7. Phase II results can help identify a dose that is safe and effective (*see* Opp. at 6, Compl. ¶ 4), and that is exactly what the Phase II data did here.

[7] The Complaint acknowledges this. Compl. ¶ 47 ("Martin's statements set forth [during the May 1, 2008 Morgan Stanley Conference] were materially false and misleading because the results of the Phase 2

an accelerated FDA filing was likely; he said that there might be a chance of an accelerated filing ("some chance" or "some probability"), but that it was not a "not a high probability."[8] Ex. M at 2. Mr. Martin's comments in response to a series of questions about what the final Phase II data would show ("whether it's statistical significance in all or parts, supported by trends, or trends with different combinations of data points") were a recitation of the kinds of results that could be seen in a clinical trial, not a representation of what the final data would be or what the interim data were. Ex. M at 2-3. His statements that he hoped that investors would understand why Elan and Wyeth started the Phase III trials when they did and that Elan and Wyeth saw enough data to "move forward," Opp. at 31, simply expressed the hope and opinion that investors would understand Elan and Wyeth's business decision to move forward with the Phase III trials. These statements are not actionable.

D. The Complaint Fails To Establish the Alleged Omissions From the May 21, 2007 Press Release Could Have Been Material to Reasonable Investors

Plaintiffs run afoul of the strict pleading requirements of the PSLRA for the independent reason that they have failed to allege any specifics as to why interim data that "failed" their alleged criteria could have rendered a characterization of the data as "strong" or "clinically meaningful" materially false.[9] Allegations similar to Plaintiffs' were found insufficient in *In re Nuvelo, Inc. Securities Litigation*, No. C 07-4056 VRW, 2008 WL 5114325 (N.D. Cal. Dec. 4, 2008). In *Nuvelo*, plaintiffs alleged defendants failed to disclose that the "secret criteria" they used to evaluate their drug's marketability were far stricter than the criteria used by the FDA,

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Study at the time of [D]efendants' *interim* analysis were not strong and spectacular as defendants said they had to be before Elan would proceed with Phase 3 trials.") (emphasis added).

[8] *See Glaser v. Enzo Biochem, Inc.*, 303 F. Supp. 2d 724 (E.D. Va. 2003) (defendant's discussion of the possibility of fast-tracking was "an opinion about the course Enzo may follow if approved by the FDA, not a guarantee that the protocol would be fast tracked," thus "[a] reasonable investor would not rely on this statement, and it is not material").

[9] It is for this reason that Plaintiffs' reliance on *In re OSI Pharms, Inc. Sec. Litig.*, No. 2:04-CV-5505, slip op. (E.D.N.Y. Mar. 31, 2007) is misplaced; unlike Plaintiffs here, plaintiffs in *OSI* had pleaded with particularity that defendant's statements about their cancer drug's efficacy were false. *See Id.* at 23.

thereby making "investment in Nuvelo more risky than investors were led to believe." *Id.* at *14. In finding these allegations too generalized to state a claim, the court stated that because plaintiffs "allege[d] no details of the supposed [secret criteria]," there was "no factual basis from which to infer that the differences between [defendants' secret criteria] and the product profile necessary for FDA approval were material" because plaintiffs had failed to "state with particularity why that difference [was] meaningful rather than trivial." *Id.*

Here, in the absence of more particularized allegations as to why interim data that "failed" Plaintiffs' criteria were comparatively deficient, Plaintiffs' claims amount to mere hindsight-based disagreement with the expert scientific assessment of the "strength" of the interim data by Elan and Wyeth's neurologists and scientists. This is not securities fraud, and similar efforts by plaintiffs have been rejected by the courts. For example, in *Glaser v. Enzo Biochem, Inc.*, 303 F. Supp. 2d at 240, the court rejected allegations that statements about a drug's efficacy were misleading because the allegations amounted to "second guess[ing] the decisions of the company" and "interject[ing] [plaintiffs'] own theories of science and bioengineering to masquerade their own misunderstanding of the clinical trial process."

In contrast, the cases relied on by Plaintiffs do not involve scientific disagreements, but instead allegations of concrete representations with distinct implications. Opp. at 19. The complaint in *In re GeoPharma Securities Litigation*, 399 F. Supp. 2d 432 (S.D.N.Y. 2005), had pleaded facts showing the distinction between the terms "drug" and "medical device" had "important consequences." *Id* at 437. In *In re Time Warner Inc. Securities Litigation*, 9 F.3d 259, 267 (2d Cir. 1993), the court found that Time Warner's later decision to raise capital by offering new shares may have rendered its prior disclosure that it would raise capital by seeking a strategic alliance misleading because a strategic alliance "would have improved the corporation's expected profit stream, and should have served to drive up the share price" while an offering of new shares "would [have] dilute[d] the ownership rights of existing shareholders, likely decrease[d] dividends, and drive[n] down the stock price." *Id.* at 268.

II. Plaintiffs Fail To State a Claim That the June 17, 2008 Press Release Was Misleading

A. Plaintiffs Fail To Respond to Defendants' Arguments That Facts Allegedly "Omitted" from the June 17, 2008 Press Release Were Not Material

None of the detailed results of the Phase II trial – whether favorable, possibly unfavorable, or neutral – were included in the June 17, 2008 press release containing the "top-line" results that drove Elan and Wyeth's business decisions. Defs' Mem. at 34-35. Plaintiffs' argument that Elan and Wyeth "cherry picked" the data for the press release is belied by both the data that were included and were not included. Defs' Mem. at 43. Moreover, Elan and Wyeth specifically advised investors in the June 17, 2008 press release that the release did not include all of the data from the trial, that the full results would be presented at ICAD on July 29, 2008, and that the results could be subject to varying interpretations. Ex. N at 2.

As to the detailed results, Elan demonstrated in its opening brief that Plaintiffs' claims about the matters that were allegedly omitted from the press release improperly were either (i) contradicted by the documents on which Plaintiffs rely, or (ii) merely the subject of varying scientific opinions and not material. *See* Defs' Mem. at 35-43. Plaintiffs dismissively recite the page count for these points but do not make any meaningful response to them. Opp. at 33.

Plaintiffs' failure to defend their grab-bag of allegations challenging the scientific opinions and judgments of Elan and Wyeth's scientists is a clear signal of the contrived nature of this case. Plaintiffs have not alleged any false or misleading statements or omissions, but, at most, that some individuals looking at the final results had different opinions about the meaning of the data. This is not sufficient to state a claim. *See* Defs' Mem. at 34-35.

B. Plaintiffs' Reliance on Stock Price Reaction To Establish Materiality Reveals Their Claims as Classic "Fraud by Hindsight"

Unable to specifically respond to Elan's arguments as to why the "omission" of certain detailed results from the June 17, 2008 release were not material, Plaintiffs assert that "[o]ne need only compare the reaction of Elan's ADR price on June 17, 2008 … with the reaction on

July 29, 2008 … to see that investors continued to be misled on June 17, 2008." Opp. at 34. This assertion reveals Plaintiffs' claims are quintessential "fraud by hindsight." *See United States v. Bilzerian*, 926 F.2d 1285, 1298 (2d Cir. 1991); *Geiger v. Solomon-Page Group, Ltd.*, 933 F. Supp. 1180, 1888 (S.D.N.Y. 1996).

Plaintiffs' selective use of analyst reports to compare some analysts' "positive" reactions to the June 17, 2008 release with other analysts' "negative" reactions to the ICAD presentation fares no better. Opp. at 34-35. Plaintiffs mischaracterize the analyst reports they cite by quoting the headlines and ignoring the content, which emphasized that the primary efficacy endpoints had not been met; noted the limitations of the post hoc analyses; discussed the issue of vasogenic edema and the higher incidence of serious adverse events in the treated patients; and acknowledged that a complete evaluation of the implications of the data had to await the presentation at ICAD. Ex. O at 2; Ex. P at 1; Ex. Q at 1; Ex. R at 1; *see also* Defs' Mem. at 20-22.

Leaving aside these flaws and inconsistencies in Plaintiffs' argument, it suffers from a more fundamental defect: evidence of a few select analysts' negative reactions is insufficient to establish the materiality of omitted information, particularly with regard to complex scientific data. *Johnson v. Pozen*, No. 1:07 CV 599, 2009 WL 426235, at *25 (M.D.N.C. Feb. 19, 2009) ("courts have observed that analysts' claims, especially on matters involving scientific knowledge, are not always reliable"); *In re Inspire Pharmaceuticals, Inc. Securities Litigation*, 515 F. Supp. 2d 631 (M.D.N.C. 2007) (analysts' speculative claims not probative of whether defendant's non-disclosure of clinical study endpoint was a material omission); *see also Cozzarelli v. Inspire Pharmaceuticals, Inc.*, 549 F.3d 618, 627 (4th Cir. 2008) ("Furthermore, the fact that some analysts relied on defendants' hopeful statements to speculate – as the analysts admitted they were doing – that Study 109 would succeed adds little to an inference of scienter. Speculation by investors and subsequent buyers' remorse cannot support an Exchange Act suit alone.").

Furthermore, regardless of whether the alleged omitted information was material, Defendants were under no duty to disclose it. Defs' Mem. at 34-35. Plaintiffs' attempts to distinguish the authorities cited by Defendants on this point are unavailing. Plaintiffs argue that in *In re Adolor Corporation Securities Litigation*, 616 F. Supp. 2d 551 (E.D. Pa. 2009), the court determined plaintiffs had not alleged facts sufficient to establish any inaccuracy, incompleteness, or misrepresentation, but they fail to mention the specific reason the court "recognized no obligation by the defendants to disclose additional information." Opp. at 35-36. The complaint in *Adolor* alleged that defendants had misleadingly omitted material information from their "top line" press release, including details of defendant's drug's efficacy in certain patient sub-groups. *Adolor*, 616 F. Supp. 2d at 569. The court first stated the general rule "that even material omissions cannot form the basis for a securities fraud claim absent a duty to disclose that information," and then determined no such duty existed where "[d]efendants consistently stated that they would only discuss the top-line results of each study" and where "[d]efendants repeatedly warned investors not to draw any final conclusions about Entereg's overall success until all three studies were complete and the full data set could be analyzed." *Id.* The court thus held that "[r]egardless of whether information about the efficacy of Entereg in patient subgroups was material, Defendants were under no obligation to disclose it." *Id.* at 570.

The same analysis applies here. As early as April 2007, Elan informed investors that Elan and Wyeth would issue "top line" Phase II results mid-2008 before issuing full detailed results at an appropriate neurology conference. Ex. E at 9. By April 2008, Elan had informed investors that full results would be released at the July 29, 2008 ICAD conference. Ex. L at 1. Elan also warned investors in the June 17, 2008 release that it "reflect[ed] preliminary analyses," that further analyses would be completed prior to the "presentation of detailed results" at ICAD, and that further analyses could lead to different interpretations of and opinions about the data. Ex. N at 2-3. The analyst reports Plaintiffs cite show that investors understood this. Ex P at 1; Ex. O at 2; Ex. R at 1; Ex. Q at 4. Investors were fully informed that the top line release did not

contain the full detailed results of the Phase II trial, and so Defendants here, as in *Adolor*, were under no duty to disclose the details Plaintiffs allege were misleadingly omitted.

Plaintiffs' attempt to distinguish *Padnes v. Scios Nova*, 1996 WL 539711 (N.D. Cal. Sept. 18, 1996), is also ineffective. Plaintiffs argue *Padnes* is not analogous because in that case plaintiffs argued that defendants misleadingly omitted alleged clinical trial design defects, as opposed to unfavorable clinical trial results. Opp. at 36. This distinction is meaningless. The plaintiffs in *Padnes* similarly alleged defendants' statements summarizing complex clinical trial results were misleading "due to omissions," and whether those alleged omissions consisted of design defects or other aspects, defendants necessarily "had to make a judgment as to which specific bits of information about the study and its conclusions to disclose." *Padnes*, 1996 WL 539711 at *5. As that court stated, it is only "[w]ith the advantage of hindsight [that] defendants' judgment as to which information to disclose is subject to challenge; however, this does not amount to facts explaining why the difference between the earlier and later statements is not merely the difference between two permissible judgments, but rather the result of a falsehood." *Id.* Plaintiffs' disagreement with Elan and Wyeth's scientists about the meaning of certain detailed aspects of the final Phase II data does not render Elan and Wyeth's June 17, 2008 "top line" release false or misleading.

III. To the Extent Plaintiffs' Claims Hinge on Defendants' Forward-Looking Statements, They Are Protected by the PSLRA Safe Harbor

While Plaintiffs are correct that the PSLRA "safe harbor" extends only to forward-looking statements, Opp. at 37, Plaintiffs mischaracterize their own allegations. Plaintiffs do not allege that the statements on May 21, 2007, July 26, 2007, and May 1, 2008 were misleading due to their historical nature. *See* Opp. at 38. Rather, they allege these statements were misleading because of what they projected about the final Phase II results, and "even a statement of present fact may become a forward-looking statement if a plaintiff's sole allegation of falsity is based on the existence of some future risk of failure." *In re Discovery Labs. Sec. Litig.*, No. 06-1820,

2006 WL 3227767, at *15 (E.D. Pa. Nov. 1, 2006); *see also id.* (a statement is properly characterized as "forward-looking" if "the alleged falsity arises from the … forward-looking aspects of the statement."). Further, though Plaintiffs argue the omissions are historical, "the omission of an historical fact … does not alter the characterization of a challenged statement," and "when the factors underlying a projection … include both assumptions and statements of known fact, and a plaintiff alleges a material fact is missing, the entire list of factors is treated as a forward looking statement." *In re Avon Products, Inc. Sec. Litig.*, No. 05 Civ. 6803 (LAK) (MHD), 2009 WL 848017, at *17 (S.D.N.Y. Feb. 23, 2009) (quoting *Ehlert v. Singer*, 245 F.3d 1313, 1318 (11th Cir. 2001)).

Plaintiffs also assert that even if the misstatements at issue were forward-looking, the safe harbor still would not apply because Plaintiffs have alleged Defendants made the misstatements with knowledge that they were false and misleading. Opp. at 40. However, Plaintiffs must so allege with particularity, *see, e.g.*, *Katz v. Household Intern, Inc.*, 91 F.3d 1036, 1039 (7th Cir. 1996) ("Although projections may be actionable if they are made with the knowledge they are incorrect or are otherwise without reasonable basis … plaintiffs still must comply with Rule 9(b)'s particularity requirements."). As explained below, Plaintiffs have not done so.

Plaintiffs' argument that the safe harbor warnings in Elan and Wyeth's May 21, 2007 and June 17, 2008 press release were "boilerplate" (Opp. at 40) ignores the actual language and substance of those warnings. The May 21, 2007 release specifically referenced the AAB-001 clinical trial for bapineuzumab; it warned of delays in the Phase III trials, "that the Phase II trials may not be successfully completed," and "that results in the proposed Phase III trial may not show that AAB-001 is safe and effective." Ex. F. By contrast, in *In re Viropharma, Inc. Securities Litigation*, No. CIV. A. 02-1627, 2003 WL 1824914 (E.D. Pa. Apr. 7, 2003), a case upon which Plaintiffs rely (Opp. at 40), the court found the safe harbor warnings were boilerplate because they stated generally "that future clinical trials may fail," and did not caution investors about the results of the specific clinical trial reported in the press release. *Id.* at *8. That the

release here did not specifically warn that the final Phase II results may fail to achieve statistical significance on the pre-defined efficacy endpoints hardly invalidates its sufficiency – "the warning need only cite important factors, and need not mention the particular factor that ultimately causes the forward-looking statement not to come true." *In re Avon Products, Inc. Sec. Litig.*, 2009 WL 848017, at *17. Moreover, the June 17, 2008 release did specifically describe the risk Plaintiffs allege materialized – that is, that "further analyses of the Phase 2 data may lead to different (including less favorable) interpretations of the data than the preliminary analyses conducted to date and/or may identify important implications of the Phase 2 data that are not reflected in these statements." Ex. N at 3.

IV. Plaintiffs' Scienter Allegations Are Implausible and Insufficient

Plaintiffs' scienter allegations are implausible and are insufficient to meet their pleading burden of showing a "strong inference" of fraudulent intent. To withstand a motion to dismiss, Plaintiffs' theory "must be more than merely plausible or reasonable – it must be cogent and compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 309 (2007). The Complaint's "motive" allegations – that Elan presented misleading study results in order to induce doctors and patients to enroll in the Phase III trials – were so obviously inadequate that Plaintiffs now even deny that they were intended as motive allegations. Defs' Mem. at 47-50; Opp. at 42 n.20 and 47 n.21. Plaintiffs also fail to respond to Defendants' reasoning as to why these allegations are completely implausible, irrespective of how Plaintiffs may choose to recharacterize them. Defs' Mem. at 49-50.

Plaintiffs fare no better with their "recklessness" or "conscious misbehavior" theory, which requires a showing of conduct that is "at the least … highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the nature was either known to the defendant or so obvious that the defendant must have been aware of it." *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000). Plaintiffs lack any particularized allegations of recklessness or plausible reasons why Elan and Wyeth would

engage in the conduct alleged by the Complaint. *See In re GeoPharma Sec. Litig.*, 411 F. Supp. 2d 434, 446 at n. 83 (S.D.N.Y. 2006) ("Courts often refuse to infer scienter, even on a recklessness theory, when confronted with illogical allegations.").

Compounding Plaintiffs' difficulties on this score is the fact that whatever scienter theories they advance must apply as well to Wyeth, which made joint decisions with Elan regarding the development of bapineuzumab and the disclosure of the results of the clinical trials. The two press releases challenged by Plaintiffs – the May 21, 2007 release announcing the commencement of the Phase III trials and the June 17, 2008 release announcing the "top line" results of the Phase II trials – were joint press releases of Elan and Wyeth. It is implausible that one public company would engage in the economically irrational and self-defeating course of conduct alleged by Plaintiffs — misleading investors for no conceivable purposes and commencing exorbitantly expensive Phase III trials on the basis of a "failed" Phase II trial. It is completely farfetched that Elan and Wyeth, two well respected public companies, would follow such an irrational and self-defeating course of action. [10]

[10] Plaintiffs attempt to bolster their scienter allegations by referring to Elan's announcement on September 29, 2009 that it had received a subpoena from the SEC requesting "records and information relating to the July 31, 2008 announcement of two Tysabri-related progressive multifocal leukoencephalopathy ("PML") cases as well as records and information relating to the July 29, 2008 announcement at the International Conference of Alzheimer's Disease concerning the Phase 2 trial data for bapineuzumab." Opp. at 4 n.7; Milkey Decl. Ex. 1 at 2. The announcement does not indicate that the SEC was seeking information about the earlier disclosures (in May 2007 and June 2008) that Plaintiffs claim were false or misleading. In any event, the cases do not support Plaintiffs' suggestion that the SEC subpoena is relevant to their fraud claims. *See, e.g.*, *In re Hutchinson Tech., Inc. Sec. Litig.*,536 F.3d 952, 962 (8th Cir. 2008) ("The mere existence of an SEC investigation does not suggest that any of the allegedly false statements were actually false and it does not render [defendant's statements] material nor does it add an inference of scienter."); *Cozzarelli v. Inspire Pharmaceuticals*, 549 F.3d 618, 628 n.2 (4th Cir. 2008) (pending SEC investigation is "too speculative to add much, if anything, to an inference of scienter."); *Frank v. Dana Corp.*, 649 F. Supp. 2d 729,742 (N.D. Ohio 2009) ("the SEC's investigation into [Defendant's] conduct does not add to the inference of scienter").

A. Plaintiffs Cannot Bootstrap Their Allegations That Defendants' Statements Were Misleading to Show Recklessness

Plaintiffs assert that because "[t]here can be no legitimate dispute that Defendants knew the interim and final results of the Phase 2 study of bapineuzumab when they made the misrepresentations at issue," they have shown recklessness. Opp. at 43. This is incorrect. To establish conscious misbehavior or recklessness under the strict pleading requirements of the PSLRA, Plaintiffs must allege "facts and circumstances that would support an inference that defendants knew of specific facts that are contrary to their public statements," *Rombach v. Chang*, 355 F.3d 164, 176 (2d Cir. 2004), and "[s]imply establishing a basis for the claim that a statement is misleading … is insufficient to raise a strong inference of fraudulent intent." *In re Tower Automotive Sec. Litig.*, 483 F. Supp. 2d 327, 341 (S.D.N.Y. 2007). *See also Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000) ("Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information."). The PSLRA does not permit Plaintiffs to bootstrap their allegations that Elan's statements were misleading to show recklessness.

With regard to the interim results, Plaintiffs "have essentially employed a pleading technique that couples a factual statement with a conclusory allegation of fraudulent intent," which is insufficient to establish recklessness. *In re DRD Gold Ltd. Sec. Litig.*, 472 F. Supp. 2d 562, 572 (S.D.N.Y. 2007) (quoting *Rombach*, 355 F.3d at 176). Plaintiffs assert in a conclusory fashion that Defendants knew bapineuzumab "failed" the interim review because it "failed to establish the superiority of bapineuzumab over placebo using the ADAS-cog and DAD tests." Opp. at 43-44. Even assuming for purposes of argument that this was properly pleaded, it would still not establish scienter because Plaintiffs fail to reference any specific reports reviewed by any defendant indicating that the "strength" of the interim data was dependent upon satisfaction of Plaintiffs' alleged criteria alone, and so Plaintiffs also fail to allege why a characterization of the data as "strong" would be reckless. *See, e.g., FL Heywood v. Cell Therapeutics, Inc.*, No. C05-0396 RSM, 2006 WL 5701625, at *7 (W.D. Wash. May 4, 2006) (allegations that statements

about a drug's interim results were misleading because defendants "must have known that increased survival rates were due to 'healthier' terminal cancer patients in Eastern Europe" were insufficient to show recklessness because they did "not amount to a particularized allegation that defendants were not indeed encouraged by the results, or that they intended to cover up the truth about STELLAR 3's outcome").

With regard to the June 17, 2008 "top-line" release, Plaintiffs allege no facts to support their assertion that Defendants had access to the full analyses of the Phase II study (or that they even existed at that time) and so knew that the June 17, 2008 press release was misleading. Opp. at 44. The release explicitly stated otherwise, warning that the analyses contained within it were preliminary, and that further analyses may reveal less favorable results. Ex. N at 2. Plaintiffs' unsupported allegation that Defendants necessarily had access to all details of the final Phase II results at the time of the June 17, 2008 release is insufficient. Opp. at 43-44. *See, e.g.*, *Teamsters Local 445 Freight Division Pension Fund v. Dynex Capital, Inc.*, 531 F. 3d 190, 196 (2d Cir. 2008) ("Teamsters' broad reference to raw data lacks even an allegation that these data had been collected into reports that demonstrated that loan origination practices were undermining the collateral's performance [and so] they have not raised an inference of scienter based on knowledge of or access to information demonstrating the inaccuracy of Dynex's public statements.").

B. Plaintiffs Have Not Adequately Alleged Recklessness or Conscious Misbehavior Because They Have Not Alleged Facts Showing That Defendants Did Not Believe the Interim Results Were Sufficiently "Strong" and "Clinically Meaningful" To Design and Commence Phase III Trials

Plaintiffs do not allege Defendants did not believe the interim data were "strong," and they otherwise fail to allege any facts as to why Elan and Wyeth could not have reasonably concluded the data warranted commencement of Phase III trials. Defs' Mem. at 51. Even if Plaintiffs' conclusory allegation that Defendants knew bapineuzumab had "failed to outperform placebo using the ADAS-cog and DAD tests" during the interim review were accepted as true, the most Plaintiffs have alleged is that the interim data were not clearly favorable in every

respect. However, "[p]eople in charge of an enterprise are not required to take a gloomy, fearful, or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business they manage." *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129-30 (2d Cir. 1994).

Even if Elan and Wyeth's announcement of the commencement of the Phase III trials amounted to a statement that the interim data were "strong" and "meaningful," such a characterization could not be considered reckless. *See In re Astrazeneca Sec. Litig.*, 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008) ("Nothing appears in the complaint showing that there was a consensus of the management that the risks of Exanta made the drug unlikely to be approved … Further, other facts, such as the approval of Exanta in Europe for some uses, made it not unreasonable for defendants to believe in their product."). Elan's decision to commence Phase III trials was made jointly with Wyeth, and reviewed with the FDA and the European regulatory authorities, which also had access to the interim data. Ex. D at 4. Even if Plaintiffs alleged (which they do not) that the only interim data that could have warranted commencement of Phase III trials were data that met Plaintiffs' alleged criteria, that would not mean that a decision by Elan and Wyeth that they should invest in Phase III trials on the basis of different data would be recklessly misleading. *See* Defs' Mem. at 52; *see also Padnes v. Scios Nova*, 1996 WL 539711, at *6 (N.D. Cal. Sept. 18, 1996) ("neither facts showing reasonable people could have disagreed with defendants' beliefs nor the mere fact that the Phase III tests were unsuccessful, even when coupled with a list of supposed protocol defects, amount to allegations that there was no reasonable basis for the opinions which were expressed").[11]

[11] In any event, as discussed *supra* at 7-13, the documents relied on in the Complaint indicate that Plaintiffs' criteria were met.

C. The Disclosure of Top-Line Results in the June 17, 2008 Press Release, with the Disclosure of Detailed Results Scheduled To Occur at ICAD at a Later Date, Does Not Show Recklessness or Conscious Misbehavior

Elan and Wyeth did exactly what they said they would do: they committed to a full presentation of the results of the Phase II trial at an important neurology conference (ICAD) on July 29, 2008 and, a few weeks before then, released the "top-line" results that drove and explained the key elements of their business planning. *See* Ex. E at 9; Ex. K at 2; Ex. L at 1. At every step of the way, both companies explained what they were doing, so that investors had a clear understanding that the June 17, 2008 press release only presented the top-line results and that the detailed results would be presented later. *Id.* This is not fraud. It is normal execution of a business plan, a typical method for disclosing results of clinical trials, and a completely plausible and logical explanation for the actions of Elan and Wyeth. This is in marked contrast to Plaintiffs' speculative and implausible theories as to why Elan and Wyeth would misrepresent the clinical results in June, only to have their misrepresentations exposed a mere six weeks later in July at a high-profile scientific conference, with their high-level executives (including Elan's CEO) in attendance. *See* Opp. at 10-11 (making the implausible and speculative arguments that Defendants decided to issue misleading results on June 17, with a correction to follow at ICAD on July 29, in order to "give investors and the public several weeks to consider the value of a potentially effective Alzheimer's drug for ApoE4 non-carriers" and to "blunt the effect of the negative Phase 2 results").

Plaintiffs' allegations that Elan and Wyeth cherry-picked the data to include in the June 17, 2008 release is obviously contradicted by the content of the press release and the later disclosures at ICAD. The June 17 release included the primary results, both favorable and unfavorable, including, most prominently, the fact that the data had failed to achieve statistical significance on its pre-specified efficacy endpoints in the total population. Ex. N at 1. Even as to the more favorable results with respect to non-carriers, Elan and Wyeth disclosed that these results were only in post hoc analyses. In addition, Elan and Wyeth disclosed that vasogenic edema was reported in the treated population with an increased frequency in carriers and at

higher doses. Ex. N at 2; Defs' Mem. at 18-20. Plaintiffs also ignore the favorable data that were not disclosed in the release, including the strong and statistically significant results from the post hoc analysis of the "completers." Defs' Mem. at 43.

At most, Plaintiffs' allegations amount to second-guessing of Elan and Wyeth's judgment about what to include in the press release. Even assuming for purposes of argument that Plaintiffs' hindsight-based, second-guessing were the "better" judgment, that would not be sufficient to state a claim for securities fraud based on recklessness.[12]

D. Plaintiffs Have Not Adequately Pleaded Recklessness Because They Have Failed To Allege Defendants Had an Obvious Duty To Disclose the Omitted Information

Plaintiffs attempt to dismiss the blinding requirement for the Phase II trial and the ICAD embargo as "excuses" used by Defendants to mislead investors. Opp. at 46. This argument is unsupported and wrong.

Plaintiffs' claims rest on the conclusory allegation that Defendants acted with fraudulent intent to mislead investors when Elan and Wyeth did not disclose detailed results of the Phase II trial (in connection with the June 17, 2008 press release) and did not disclose any of the results of the interim review (in connection with the May 21, 2007 press release). Plaintiffs do not claim that either of these releases contained affirmative misstatements, but only that they were rendered misleading because Elan and Wyeth did not include enough information in them. In these circumstances – where a complaint alleges conscious misbehavior or recklessness in omitting material information – authority in this Circuit holds that the plaintiff must allege facts

[12] *See In re GeoPharma Sec. Litig.*, 411 F. Supp. 2d 434, 436 (S.D.N.Y. 2006) ("It is entirely possible for a defendant to make an honest but negligent mistake in judging how much detail needs to be included in public statements in order to avoid misleading the market," but the securities laws were meant "to punish knowing fraud or reckless behavior, not mistakes that arise from negligent or even grossly negligent behavior"); *Padnes* 1996 WL 539711, at *5 (fraud allegations insufficient where plaintiffs failed to allege "facts explaining why the difference between the earlier and later statements is not merely the difference between two permissible judgments, but rather the result of a falsehood").

establishing there was an obvious duty to disclose the omitted information**.** *In re GeoPharma Sec. Litig.*, 411 F. Supp. 2d 434, 446 (S.D.N.Y. 2006). Plaintiffs have not alleged such facts.

The court in *GeoPharma* cited *Kalnit v. Eichler*, 264 F. 3d 131 (2d Cir. 2001), in which the Second Circuit drew a distinction between affirmative misstatements and misleading omissions, and held that "[b]ecause … this case does not present facts indicating a clear duty to disclose, plaintiff's scienter allegations do not provide *strong* evidence of conscious misbehavior or recklessness." *Id.* at 144 (emphasis in original). The court in *Medis Investor Group v. Medis Tech Ltd.*, 586 F. Supp. 2d 136 (S.D.N.Y. 2008), cited both *GeoPharma* and *Kalnit* for this rule, and commented that it was necessary to "ensure[] that fraudulent intent cannot be imputed to a company every time a public statement lacks detail." *Id.* at 144. The court then determined that the complaint in that case had failed to establish that defendants had an "obvious duty" to disclose the omitted detailed sales information because of a company policy instructing that such information should not be disclosed. As the court noted, "[p]laintiff never explains why taking such a tack with regard to sensitive sales information [was] reckless." *Id.*

What Plaintiffs here call "excuses" are in fact legitimate reasons for Defendants' actions that appear on the face of the Complaint and documents cited in the Complaint. Elan and Wyeth repeatedly told investors that, in order to preserve the blinded nature and thus the scientific integrity of the Phase II trial, they were not going to announce the criteria for the interim review or the data from the interim review. Compl. ¶ 37; Ex. D at 4-6; Ex. F at 1; Ex. M at 2. Plaintiffs argue that the disclosure of the results of the interim review would not have compromised the trial's blinded status as long as patients and doctors in the trial were not told whether they were receiving bapineuzumab or placebo (Opp. at 45), but Plaintiffs offer no factual or logical support for their erroneous view of scientific standards and practices. Nor do they cite any investor or analyst who disputed that disclosing results of the trial would have compromised the scientific validity of the trial. And, contrary to Plaintiffs' assertion, Elan and Wyeth did not "elect[] to speak to investors and convey that the interim review had met Elan's objective criteria." Opp. at 45. Elan and Wyeth announced a major business decision to commence Phase III trials, saying

that it "was based on the seriousness of the disease and the totality of what the companies have learned from their immunotherapy programs, including a scheduled Interim look at data from an ongoing Phase 2 study, which remains blinded." They further warned, "No conclusion about the Phase 2 study can be drawn until the study is completed and the final data are analyzed and released in 2008." ¶ 39; Ex. F. Elan and Wyeth could not have been clearer to investors and the general public that they were not conveying anything about the interim data, including whether the data did or did not meet internal criteria that had never been publicly disclosed. There was no "obvious duty" to disclose information regarding internal criteria in these circumstances.

Elan and Wyeth also had legitimate business reasons for disclosing the final Phase II results in the manner they did. They had already committed to present the full results at ICAD on July 29, 2008, but they elected to disclose the material top-line results that drove their business planning when they became reasonably available, even though, as disclosed in their press release, Elan and Wyeth were continuing to review and analyze the data pending the full presentation at ICAD.[13] Ex. N at 2. Notably, none of the analyst reports relied on in the Complaint questioned the practice of issuing a "top line" release pending a full presentation of the data at a high-profile scientific conference. Thus, as in *Cozzarelli v. Inspire Pharmaceuticals*, 549 F.3d 618 (4th Cir. 2008), "legitimate business motivations explain[ed] each of the facts alleged in the complaint more convincingly than plaintiffs' tenuous theory of wrongful intent." *Id.* at 626.

Plaintiffs' most original argument on scienter is that it is "in no way inconsistent" for Defendants to have had both legitimate *and* fraudulent motivations for not disclosing additional information concerning the Phase II interim and final results. Opp. at 46. This makes no sense. These legitimate motivations are "plausible nonculpable explanations for the defendant's

[13] Plaintiffs' assertion that the ICAD embargo is "outside the pleadings" is meritless in light of the specific materials relied upon in their Complaint. Opp. at 46. Defendants cited a statement in an April 28, 2008 Natixis Bleichroeder report that "ICAD will impose an embargo on most of the data." Defs' Mem. at 16 (quoting Ex. L at 1). This report was quoted in the Complaint, and the specific language cited by Defendants was a clause in a sentence that the Complaint partially quoted. Compl. ¶ 45; Ex. L at 1.

conduct," *Tellabs*, 551 U.S. at 310, that are far more compelling than Plaintiffs' farfetched theories about defrauding patients and doctors into participating in clinical trials (Opp. at 8), starting hugely expensive Phase III trials on the basis of failed Phase II interim data because "there was always the chance that the final results of the Phase 2 trial would be better" (*id*.), and spending enormous amounts of money to get the Phase III trials started and ended quickly so that Elan and Wyeth would have "a chance of burying the Phase 2 results and seeking FDA approval" (*id.*) while at the same time presenting the Phase 2 results at a high-profile neurology conference (*id*. at 10). Plaintiffs' theories are both internally inconsistent and implausible.

E. Plaintiffs Cannot Rely on Any "Core Operations" Presumption of Scienter

To establish the scienter of the individual defendants, Plaintiffs rely on cases holding that knowledge of the alleged falsity of public statements regarding a company's "core business operations" can be attributed to senior executives of the company. Opp. at 49-50. As a preliminary matter, it is doubtful that, for purposes of pleading scienter, the "core operations" assumption survived the PSLRA and *Tellabs*. *See In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp. 2d 266, 294 (S.D.N.Y. 2006) ("To the extent that this 'core operations' method of pleading conscious misbehavior or recklessness is viable after the PSLRA, plaintiffs must provide more facts to support a strong inference that any misstatements by defendants regarding PI must have been made with scienter."); *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 867 (5th Cir. 2003) (rejecting allegation that failure of company's core business evidences defendant's knowledge that they were misrepresenting company's prospects for success); *In re Read-Rite Corp. Sec. Litig.*, 335 F.3d 843, 848 (9th Cir. 2003) (rejecting "core operations" method of pleading scienter in light of PSLRA).

In any case, a "core operations" assumption of scienter could not apply here. Because Elan and Wyeth jointly made decisions about the development of bapineuzumab and the disclosure of the results of the trials, any scienter allegations would have to apply as well to Wyeth. Plaintiffs' "core operations" argument makes no sense whatever as applied to Wyeth,

which is a broadly diversified pharmaceutical company with many consumer brands, prescription drugs and vaccines, and numerous other research and development programs. *See, e.g.*, Ex. C (Oct. 1, 2006 Wyeth conference call transcript detailing Wyeth's research and development programs).

V. The Complaint Fails To State a Claim Under Section 20(a)

Plaintiffs cannot state a claim under Section 20(a) because they have failed to plead an underlying violation of the securities laws. Further, though Plaintiffs assert that "the Second Circuit has not defined what is meant by the requirement that a controlling entity be a 'culpable participant,'" Opp. at 51, as this Court found in *In re Vivendi Universal, S.A.*, the Second Circuit has held that "allegations of Section 20(a) liability must show that the controlling person was in some meaningful sense a culpable participant in the fraud perpetrated by the controlled person." No. 02 Civ. 5591 (RJH), 2004 WL 876050, at *10 (S.D.N.Y. Apr. 22, 2004) (quoting *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 170 (2d Cir. 2000)); *see also ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87 (2d Cir. 2007). This element "is subject to the PSLRA's heightened pleading requirements, and requires particularized allegations that defendants acted with scienter." *In re Regeneron Pharm., Inc. Sec. Litig.*, No. 03 Civ. 311 RWS, 2005 WL 225288, at *11 (S.D.N.Y. Feb. 1, 2005). Here, Plaintiffs have failed to plead with particularity that Mr. Ekman or Mr. Martin acted with scienter. They allege no specific facts relating to the knowledge of either of them, much less that they acted with fraudulent intent.

VI. Leave To Amend Should Be Denied

Plaintiffs' boilerplate request for leave to amend "in the event the Court determines the Complaint is deficient in any respect" should be denied. Opp. at 53. Plaintiffs are "not entitled to an advisory opinion from the Court informing them of the deficiencies in the complaint and then an opportunity to cure those deficiencies." *Bellikoff v. Eaton Vance Corp.*, 481 F.3d 110, 118 (2d Cir. 2007). It is within the Court's discretion to deny leave "where plaintiffs made only a bare request in an opposition to a motion to dismiss," *Copeland ex rel. NBTY, Inc. v.*

Rudolph, 160 Fed. Appx. 56, 59 (2d Cir. 2005), or where amendment would be futile. *John Hancock Mut. Life Ins. Co. v. Amerford Int'l. Corp.*, 22 F.3d 458, 462 (2d Cir. 1994). Further, "where a plaintiff is unable to allege any fact sufficient to support its claim, leave should be denied." *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F. 2d 42, 48 (2d Cir. 1991).

CONCLUSION

For the foregoing reasons, the Defendants' motion to dismiss should be granted and the Complaint should be dismissed with prejudice.

Dated: New York, New York
April 16, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Jaculin Aaron, hereby certify that on April 16, 2010, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such public filing to all counsel registered to receive such notice.

s/ Jaculin Aaron
Jaculin Aaron